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Federal Register Notices 49685 & 49686 dated September 28, 2001

Dear Dr. Stokes,

with regard to Federal Register Notices 49685 and 49686 dated September 28, 2001 (Vol. 66, No. 198) I would like to send you the two official comments of the BgVV:

1. ***Federal Register / Vol. 66, No. 198 / Friday, September 28, 2001 / Notices, 49685***
   EPISKIN™, EpiDerm™, and Rat Skin Transcutaneous Electrical Resistance Methods: In Vitro Test Methods Proposed for Assessing the Dermal Corrosivity Potential of Chemicals; Notice of Availability of a Background Review Document and Proposed ICCVAM Test Method Recommendations and Request for Public Comment

   The Background Review Document of the NTP is an excellent review with respect to the development and validation of alternative methods for the replacement of skin corrosion testing with rabbits. The test methods described and commented correspond to the respective methodologies as laid down in the new test guideline B. 40 SKIN CORROSION in the European Commission Directive 2000/33/EC of 25 April 2000. The new methods are appropriate to be used for the assessment of skin corrosion within the tiered testing and assessment strategy for skin irritation/corrosion as defined within the Globally Harmonised Classification System (GHS) of the OECD and the Annex of the revised OECD Test Guideline 404.

2. ***Federal Register / Vol. 66, No. 198 / Friday, September 28, 2001 / Notices, 49686***
   Report of the International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity; Guidance Document on Using Data to Estimate In Vivo Starting Dose for Acute Toxicity: Notice of Availability and Requst for Public Comment

   We highly support the idea of using *in vitro* data for estimation of the *in vivo* starting dose for animal tests on acute toxicity. The possibility to predict the suitability of a limit test prior to any testing for

acute toxicity can help to significantly reduce the number of test animals. In addition, the possibility of a rough estimation whether or not a chemical is to be considered as probably exhibiting a high toxic potential by means of a combination of *in vitro* data and SAR considerations on toxicokinetic properties, should be evaluated in order to fit into screening procedures for large lists of chemicals lacking information on their toxicological properties.

With the best regards
Yours sincerely

/s/

Dr. med. Horst Spielmann
Direktor und Professor
Head of ZEBET